

510(k) Summary
for the
Everest Spinal System

This 510(k) summary for the Everest Spinal System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :

K2M, Inc.
751 Miller Drive SE,
Suite F1
Leesburg, VA 20175

Contact Person :

Nancy Giezen
K2M, Inc.
Telephone: 703-777-3155

Date Prepared: 09/26/13

OCT 03 2013

2. Tradename:

Everest Spinal System

Common Name:

Spinal Fixation System

Classification Name:

Spinal Interlaminar Fixation Orthosis (21CFR 888.3050)

Pedicle Screw Spinal System (888.3070)

Device Product Code:

KWP, MNI

Regulatory Class:

Class II

3. Predicate or legally marketed devices which are substantially equivalent :

- K2M Everest Spinal System (K103440, K120656)
- K2M Range Spinal System (K052398, K070229, K080792, K081381, K112037, K130330)
- NuVasive SpherX (K092287)
- Globus Resolve (K083416)

4. Description of the device:

The Everest Spinal System is a top-loading, multiple component, posterior (thoracic-lumbar) spinal fixation system which consists of pedicle screws, rods, locking set screws, and hooks.

Materials: The devices are manufactured from Titanium Alloy and Cobalt Chrome per ASTM and ISO standards.

Function: The system functions as an adjunct to fusion to provide immobilization and stabilization of the posterior thoracic and lumbar spine.

The purpose of this 510(k) submission is to add minimally invasive implants.

5. Intended Use:

The EVEREST Spinal System may be used in conjunction with the RANGE® (MESA® and DENALI®) Spinal Systems, all of which are cleared for the following indications:

Non-cervical, pedicle screw fixation devices for posterior stabilization as an adjunct to fusion for the following indications: Trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. It is also indicated for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Non-cervical, non-pedicle spinal fixation devices intended for posterior or anterolateral thoracolumbar screw stabilization as an adjunct to fusion for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

The minimally invasive components of the Everest Spinal System were mechanically tested and compared to predicate devices. The subject device performed equally to or better than these systems in static compression, static torsion and dynamic compression in accordance with ASTM F1717. The design features and sizing of the components were also compared and found to be substantially the same as these systems.

There are no significant differences between the Everest Spinal System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 3, 2013

K2M, Incorporated
Ms. Nancy Giezen
751 Miller Drive Southeast
Leesburg, Virginia 20175

Re: K132361

Trade/Device Name: Everest Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, KWP
Dated: August 6, 2013
Received: August 7, 2013

Dear Ms. Giezen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act): 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132361

Device Name: Everest Spinal System

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colp O'Neill
for RPJ
(Division Sign-off)
Division of Orthopedic Devices
510(k) Number: K132361